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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,106	09/28/2000	Randal K. Buddington	2343-104-27	8636
7590	04/04/2005		EXAMINER	
Patent Prosecution Services Piper Marbury Rudnick & Wolfe LLP 1200 Nineteenth Street, N.W. Washington, DC 20036-2412				OH, SIMON J
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 04/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/671,106	BUDDINGTON ET AL.
	Examiner Simon J. Oh	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 February 2005.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 18-20,23,24,27,30,31,33,34,37 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 18-20,23,24,27,30,31,33,34,37 and 41-46 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment, response, and literature excerpts, all received on 17 February 2005.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 18-20, 23, 24, 27, 30, 31, 33, 34, and 37 under 35 U.S.C. 103(a) over Paul *et al.* and Van Loo *et al.* is maintained.

Claims 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Paul *et al.* and Van Loo *et al.*

The Paul *et al.* patent teaches an orally administered composition for promoting gastrointestinal health comprised of an effective amount of dietary fiber (See Abstract; and Column 3, Lines 39-57). The dietary fiber is a member selected from the group consisting of fructo-oligosaccharides, such as inulin, pectins, pectic polysaccharides, and mannans such as guar gum (See Column 4, Lines 1-10). The Paul *et al.* patent further states that the disclosed compositions can be used for treating conditions facilitated by infections caused by pathogenic microorganisms such as *E. coli*, *Salmonella*, and *Candida* (See Column 16, Lines 21-26).

The Paul *et al.* patent does not make mention of the degree of polymerization of a dietary fiber.

The Van Loo *et al.* patent teaches a fructan-containing composition with an average degree of polymerization of 15 or higher (See Column 4, Lines 22-28; and Claim 1). The Van Loo *et al.* patent also discloses chicory inulin with an average degree of polymerization of about 25 (See Claim 18). The daily doses effective in providing prevention and treatment of colon cancer range from 0.01 to 2 g/kg of body weight (See Column 5, Lines 51-54).

One of ordinary skill in the art would be motivated to combine the two prior art references as they both broadly show that the administration of dietary fiber, such as inulin, is beneficial for the gastrointestinal health of a subject in need thereof. As the compositions in both prior art references have similar various effects which are known in the art to be beneficial to a subject, one of ordinary skill in the art would have a reasonable chance of success in combining the two references. Such effects include a reduction of intestinal transit time, a decrease of the intestinal pH, a bifidus stimulating activity in the colon, bulking of the stool, increase in stool frequency, and an improvement in lipid metabolism (See Paul *et al.*, Columns 2, 3, and 7-11; and Van Loo *et al.*, Column 2). Thus, the instantly claimed invention is *prima facie* obvious.

#### ***Response to Arguments***

Applicant's arguments filed 17 February 2005 have been fully considered but they are not persuasive.

The examiner appreciates the efforts made by the applicants to further clarify what is meant by "local infection" and "systemic infection". However, it is the position of the examiner

that the prior art still reads on the instantly claimed invention. The methods and compositions of Paul *et al.* are used to promote the health of the gastrointestinal system. In light of the definitions given by the applicant, the gastrointestinal tract is not one small area or one singular organ. It is an organ system consisting of several organs, which, if it were infected as a whole, in the view of the examiner, would sufficiently read on what has been defined as a systemic infection. All pending claims are therefore rejected.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1615

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SUPERVISORY PATENT EXAMINER  
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